DETAILED ACTION

Claims 1-14 are presented for examination.

Acknowledgment is made of the present application as a National Stage (371) entry of PCT Application No. PCT/US05/09069, filed March 18, 2005, which claims benefit under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/554,228, filed March 18, 2004.

Applicant's Information Disclosure Statement (IDS) filed May 22, 2007 (one page total) has been received and entered into the present application. As reflected by the attached, completed copy of form PTO-1449, the Examiner has considered the cited references.

Requirement for Restriction/Election

Applicant's election of the invention of Group I (claims 1-8), directed to a method for regulating food intake by administering a compound to a subject wherein the compound affects the activity of AMPK (AMP-activated protein kinase), and the election of the compound C75 as the single disclosed species of compound that affects the activity of AMPK for examination, to which examination on the merits will be restricted, in the reply filed February 19, 2010, is acknowledged by the Examiner. Because Applicant did not distinctly and specifically point out the supposed errors in the requirement, the election has been treated as an election **without traverse** (MPEP §818.03(a)).

Therefore, for the reasons above and those made of record at p.2-8 of the previous Office Action dated January 19, 2010, the requirement remains proper and is hereby made **FINAL**.

Claims 3 and 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being directed to non-elected subject matter, there being no allowable generic or linking claim.

The claims that are drawn to the elected invention and elected species are claims 1-2 and 4-8 and such claims are herein acted on the merits.

Objection to the Oath/Declaration

The declaration filed October 26, 2007 is defective because the information regarding inventor Bun-Kyoung Kim contains handwritten changes at p.3 that have not been initialed or dated by the individual(s) who executed the declaration. A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by serial number and filing date is required. Please reference MPEP §§602.01 and 602.02.

Objection to the Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is also reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to for using legal phraseology, such as “means” and “applicants”, repeatedly throughout the summary, as well as for providing extraneous background information regarding obesity that is not necessary to provide a concise description of the claimed invention. Correction is required. See MPEP § 608.01(b).

Objection to the Claims

Claim 1 is objected to for failing to define the acronym “AMPK” at its first occurrence in the claims.

Claim 5 is objected to for failing to conclude with a period.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Loftus et al. (WO 01/60174; 2001).

Loftus et al. teaches methods for promoting weight loss by inhibiting feeding behavior, achieved via any one or more of the disclosed methods, including a method for inducing weight loss via the administration to an animal a compound that reduces the expression and/or secretion of neuropeptide Y (NPY), wherein the compound may be an inhibitor of fatty acid synthase (FAS), including substituted α-methylene-β-carboxyl-γ-butyrolactones, or inhibitors of malonyl coenzyme A decarboxylase (MCD) (p.4,

l.23-p.5, l.3). Loftus et al. specifically discloses that FAS inhibitors, particularly the α-methylene-β-carboxyl-γ-butyrolactone C-75, functions to induce weight loss by inhibiting feeding (p.6, l.3-5). Ex. 1A of Loftus et al. confirmed this finding after administering 15 mg/kg by single intraperitoneal injection to male BALB/c mice and observing a greater than 90% reduction in food intake over the first 24 hours following administration (p.17, l.11-17 and l.26-28). Loftus et al. further teaches that the methods may be used for the treatment of animals, including vertebrates, especially mammals, including poultry, swine, cattle, sheep, etc. (p.13, l.6-14), as well as human therapy (p.12, l.10-12).

Though it is noted that Loftus et al. does not expressly teach that the C75 compound affects the activity of AMPK (claim 1) either via inhibition of AMPK (claim 5) or stimulation of AMPK (claim 6), it is noted that the compound of Loftus et al. is identical to the compound recited in Applicant's instant claims and is used in the same manner (i.e., via administration to a subject) as that instantly claimed. Therefore, the method of treatment of Loftus et al. must necessarily possess the same functions in affecting the activity of AMPK (as in claim 1) via inhibiting (claim 5) or stimulating (claim 6) AMPK as that instantly claimed whether recognized by the patentee or not because products of identical chemical composition cannot have mutually exclusive properties when used in exactly the same manner. In other words, if the prior art teaches the identical chemical and/or physical structure of the claimed compound and further teaches the identical manner of using the same, the properties that Applicant discloses and/or claims are necessarily present. See MPEP §2112. Furthermore, it is generally well settled in the courts that a mechanistic property of a chemical compound, when administered under identical conditions, is necessarily present, despite the fact that such a mechanistic property may not have been readily apparent to, or recognized by, one of ordinary skill in the art at the time of the disclosure.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe necessarily includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden

is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized this necessarily present disclosure at the time of the invention, but only that the subject matter is, in fact, necessarily present in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, Loftus et al. teaches the same compound as that presently claimed for use in the same manner to the same host and for the same objective as that instantly claimed, and, therefore, the resultant effect of affecting the activity of AMPK (either through inhibition or stimulation of AMPK) must also be the present, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, the compound of Loftus et al. does not possess these same characteristics as instantly claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 4-8 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 19-20 of U.S. Patent Application No.

10/533,311 in view of Kuhajda et al. (U.S. Patent No. 5,981,575; 1999).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited patents are not considered patentably distinct from each other because the pending claims are anticipated and/or rendered obvious by the copending claims.

The copending claims provide for a method of inhibiting cancer development in pre-cancerous cells comprising the administration to a subject in need thereof of an effective amount of a fatty acid synthase inhibitor, wherein the subject may be a mammal or human, and further wherein the fatty acid synthase inhibitor is tetrahydro-3-methylene-2-oxo-5-n-acyl-4-furancarboxylic acid, which is synonymous with "C-75" as used in the instant claims, as evidenced by Kuhajda et al. (U.S. Patent No. 5,981,575; 1999) at col.12, Ex.1C.

Though the copending claims do not expressly teach that the C75 compound regulates food intake (claim 1), affects the activity of AMPK (claim 1) either via inhibition of AMPK (claim 5) or stimulation of AMPK (claim 6), it is noted that the copending claims teach a compound that is identical to the compound recited in Applicant's instant claims and is used in the same manner (i.e., via administration to a subject) as that instantly claimed. Therefore, the method of treatment of the copending and/or patented claims must necessarily possess the same functions in regulating food intake (claim 1) or affecting the activity of AMPK (as in claim 1) via inhibiting (claim 5) or stimulating (claim 6) AMPK as that instantly claimed whether recognized by the patentee or not because products of identical chemical composition cannot have mutually exclusive properties when used in exactly the same manner. See MPEP §2112. Furthermore, it is generally well settled in the courts that a mechanistic property of a chemical compound,

when administered under identical conditions, is necessarily present, despite the fact that such a mechanistic property may not have been readily apparent to, or recognized by, one of ordinary skill in the art at the time of the disclosure.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe necessarily includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized this necessarily present disclosure at the time of the invention, but only that the subject matter is, in fact, necessarily present in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, the copending claims teach the same compound as that presently claimed for use in the same manner to the same host as that instantly claimed, and, therefore, the resultant effect of regulating food intake or affecting the activity of AMPK (either through inhibition or stimulation of AMPK) must also be the present, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, the copending claims does not possess these same characteristics as instantly claimed.

Accordingly, rejection of claims 1-2 and 4-8 is proper over claims 1-17 and 19-20 of U.S. Patent Application No. 10/533,311 as claiming obvious and unpatentable variants. The rejection is provisional because the claims have not, in fact, yet been patented.

Claims 1-2 and 4-8 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent Application No. 12/309,422 in view of Loftus et al. (WO 01/60174; 2001).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited patents are not considered patentably distinct from each other because the pending claims are anticipated and/or rendered obvious by the copending claims.

The copending claims provide for a method of decreasing the food intake of a subject comprising the administration of a compound that increase FAO, wherein the compound is not a fatty acid, wherein the subject may be a human or animal. The copending claims further provide for the compound to be a stimulator of CPT-1. Though the copending claims do not specifically recite that the compound increases FAO and also may be a stimulator of CPT-1 is C-75, the copending specification defines the compound C-75 as a compound that functions to stimulate CPT-1 activity that leads to an increase in FAO (p.1, para.1). In the instant case, the copending specification is relied upon to define the compound that "increases FAO" and "is a CPT-1 stimulator", which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patient claim. *Toro Co. v. White Consol. Indus., Inc.* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

The copending claims fail to specifically teach the treatment of mammals.

Loftus et al. teaches that FAS inhibitors, particularly the α-methylene-β-carboxyl-γ-butyrolactone C-75, functions to induce weight loss by inhibiting feeding (p.6, l.3-5). Ex. 1A of Loftus et al. confirmed this finding after administering 15 mg/kg by single intraperitoneal injection to male BALB/c mice and

observing a greater than 90% reduction in food intake over the first 24 hours following administration (p.17, l.11-17 and l.26-28). Loftus et al. further teaches that the methods may be used for the treatment of animals, including vertebrates, especially mammals, including poultry, swine, cattle, sheep, etc. (p.13, l.6-14), as well as human therapy (p.12, l.10-12).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* to employ the copending method in the treatment of, specifically, mammals because Loftus et al. teaches that the C-75 compound is effective to inhibiting feeding (i.e., decrease food intake as recited in the instant claims) in both humans and various types of animals, including mammals, such as poultry, swine, etc., such that the skilled artisan would have a reasonable expectation of successfully decreasing food intake in a mammalian subject.

Accordingly, rejection of claims 1-2 and 4-8 is proper over claims 1-4 of U.S. Patent Application No. 12/309,422 as claiming obvious and unpatentable variants. The rejection is provisional because the claims have not, in fact, yet been patented.

Claims 1-2, 4-5 and 7-8 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent Application No. 12/558,313 in view of Loftus et al. (WO 01/60174; 2001).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited patents are not considered patentably distinct from each other because the pending claims are anticipated and/or rendered obvious by the copending claims.

The copending claims provide for a method of inducing weight loss in an animal comprising administering to said animal a compound that inhibits feeding activity in the animal wherein said compound in an inhibitor of 5'-AMP-activated protein AMP kinase (AMPK), wherein the compound decreases activity of 5'-AMP-activated protein AMP kinase, and increases the levels of malonyl-CoA in said animal.

The copending claims fail to specifically teach the use of C-75 or the treatment of mammals.

Loftus et al. teaches that FAS inhibitors, particularly the α-methylene-β-carboxyl-γ-butyrolactone C-75, functions to induce weight loss by inhibiting feeding (p.6, l.3-5) and also leads to increased levels of malonyl-CoA (p.8, l.9-11). Ex. 1A of Loftus et al. confirmed this finding after administering 15 mg/kg by single intraperitoneal injection to male BALB/c mice and observing a greater than 90% reduction in food intake over the first 24 hours following administration (p.17, l.11-17 and l.26-28). Loftus et al. further teaches that the methods may be used for the treatment of animals, including vertebrates, especially mammals, including poultry, swine, cattle, sheep, etc. (p.13, l.6-14), as well as human therapy (p.12, l.10-12).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* to employ C-75 as the AMPK inhibitor that increases malonyl-CoA in the copending method because, as evidenced by Loftus, C-75 is one of such inhibitors that functions to increase malonyl-CoA and was known in the art to have such properties. As a result, the use of such a compound in the copending method would have naturally commended itself to the skilled artisan motivated to employ compounds that function in the desired manner recited in the copending claims. Further, one of ordinary skill in the art would have also found it *prima facie* obvious to employ the copending method in the treatment of, specifically, mammals (including humans), because Loftus et al. teaches that the C-75 compound is effective to inhibiting feeding (i.e., decrease food intake as recited in the instant claims) in both humans and various types of animals, including mammals, such as poultry, swine, etc., such that the skilled

artisan would have a reasonable expectation of successfully decreasing food intake in a mammalian or human subject.

Accordingly, rejection of claims 1-2, 4-5 and 7-8 is proper over claims 1-2 of U.S. Patent Application No. 12/558,313 as claiming obvious and unpatentable variants. The rejection is provisional because the claims have not, in fact, yet been patented.

Claims 1-2 and 4-8 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent Application No. 12/755,944 or rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-2 of U.S. Patent No. 7,459,481 or claims 1-9 and 14 of U.S. Patent No. 5,981,575, each alternatively in view of Loftus et al. (WO 01/60174; 2001).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited patents are not considered patentably distinct from each other because the pending claims are anticipated and/or rendered obvious by the copending and/or patented claims.

The ‘944 claims provide for a method of inducing weight loss comprising administering an agent that stimulates carnitine palmitoyl transferase-1 (CPT-1) activity or a method for stabilizing weight comprising chronic administration of an agent that stimulates CPT-1 activity in an amount that does not significantly inhibit fatty acid synthase.

The ‘481 claims provide for a method of inducing weight loss comprising administering to a patient an effective amount of an agent that stimulates carnitine palmitoyl transferase-1 (CPT-1) activity

in an amount that does not significantly inhibit fatty acid synthase or a method for stabilizing weight comprising chronic administration to a patient of an effective amount of an agent that stimulates CPT-1 activity in an amount that does not significantly inhibit fatty acid synthase.

Though the copending and/or patented claims do not specifically recite that the agent that stimulates carnitine palmitoyl transferase-1 (CPT-1) is C-75, note that the '944 patent specification defines the compound C-75 as a direct stimulator of CPT-1 (p.6, para.2) and the '481 patent specification also defines the compound C-75 as a direct stimulator of CPT-1 (col.4, l.31-39). In the instant case, the '944 and '481 patent specifications are relied upon to define the term "agent that stimulates carnitine palmitoyl transferase-1", which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patient claim. *Toro Co. v. White Consol. Indus., Inc.* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

The patented claims clearly provide for methods for inducing weight loss in an animal comprising administering to the animal a compound that reduces fatty acid synthase activity in adipocytes or liver cells, wherein said compound is not a fat or metabolizable product thereof. The patented claims further provide for a method of treating a condition responsive to reduction in adipose tissue mass in an animal comprising administering a composition that reduces fatty acid synthase activity in adipocytes or liver cells, as well as a method for inducing weight loss in an animal comprising administering to the animal a composition according to patent claim 10, which provides for composition comprising a 5-substituted 2-oxo-methylene-4-furancarboxylic acid, wherein the substituent is, *inter alia*, a saturated linear alkyl group of 3-18 carbons, which clearly provides for a linear alkyl group of 8 carbons, which provides for the compound C-75 as evidenced by the structure set forth in Ex.1C at col.12. Though the patented claims do not specifically recite that the inhibitor of fatty acid synthase is C-75, the patent disclosure clearly defines the compound C-75 as an inhibitor of fatty acid synthase (ex.5, col.16). In the instant case, the patent specification is relied upon to define the term "compounds which reduce fatty acid synthase" or "inhibitor

of fatty acid synthase", which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patient claim. *Toro Co. v. White Consol. Indus., Inc.* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

The copending or patented claims fail to teach that the compound (i.e., C75) affects the activity of AMPK (claim 1) via inhibition (claim 5) or stimulation (claim 6) of AMPK, or that the compound is effective to regulate food intake (claim 1) or the administration of the compound to a human or mammal other than a human (claims 7-8).

Though the copending or patented claims do not expressly teach that the C75 compound affects the activity of AMPK (claim 1) either via inhibition of AMPK (claim 5) or stimulation of AMPK (claim 6), it is noted that the copending claims teach a compound that is identical to the compound recited in Applicant's instant claims and is used in the same manner (i.e., via administration to a subject) as that instantly claimed. Therefore, the method of treatment of the copending and/or patented claims must necessarily possess the same functions in affecting the activity of AMPK (as in claim 1) via inhibiting (claim 5) or stimulating (claim 6) AMPK as that instantly claimed whether recognized by the patentee or not because products of identical chemical composition cannot have mutually exclusive properties when used in exactly the same manner. See MPEP §2112. Furthermore, it is generally well settled in the courts that a mechanistic property of a chemical compound, when administered under identical conditions, is necessarily present, despite the fact that such a mechanistic property may not have been readily apparent to, or recognized by, one of ordinary skill in the art at the time of the disclosure.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe necessarily includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no

requirement that a person of ordinary skill in the art would have recognized this necessarily present disclosure at the time of the invention, but only that the subject matter is, in fact, necessarily present in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, the copending and/or patented claims teach the same compound as that presently claimed for use in the same manner to the same host as that instantly claimed, and, therefore, the resultant effect of affecting the activity of AMPK (either through inhibition or stimulation of AMPK) must also be the present, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, the compound of the copending and/or patented claims does not possess these same characteristics as instantly claimed.

Loftus et al. teaches that FAS inhibitors, particularly the α-methylene-β-carboxyl-γ-butyrolactone C-75, functions to induce weight loss by inhibiting feeding (p.6, l.3-5). Ex. 1A of Loftus et al. confirmed this finding after administering 15 mg/kg by single intraperitoneal injection to male BALB/c mice and observing a greater than 90% reduction in food intake over the first 24 hours following administration (p.17, l.11-17 and l.26-28). Loftus et al. further teaches that the methods may be used for the treatment of animals, including vertebrates, especially mammals, including poultry, swine, cattle, sheep, etc. (p.13, l.6-14), as well as human therapy (p.12, l.10-12).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ the methods of the copending and/or patented claims for effecting an inhibition (i.e., "regulating" as instantly claimed) of food intake and, thus, inducing weight loss or stabilizing weight because Loftus et al. specifically teaches that the compound C75 functions to induce weight loss by inhibiting feeding (i.e., decreasing food intake) when administered to a subject in need thereof.

Furthermore, such a person would have been further motivated to employ such methods in humans or mammals other than humans because Loftus et al. teaches that the ability of the compound C75 to modulate food intake and weight is effective for the treatment of a wide variety of animals, including mammals (i.e., poultry, swine, etc.), as well as humans.

Accordingly, rejection of claims 1-2 and 4-8 is proper over claims 1-2 of U.S. Patent Application No. 12/755,944 or claims 1-2 of U.S. Patent No. 7,459,481 or claims 1-9 and 14 of U.S. Patent No. 5,981,575, as claiming obvious and unpatentable variants. The rejection over the '944 application is a provisional rejection because the claims have not, in fact, yet been patented.

Conclusion

Rejection of claims 1-2 and 4-8 is proper.

Claims 3 and 9-14 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

April 23, 2010